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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/787,334   | 06/19/2001  | Sylvain Chemtob      | 2861-4003           | 9475             |
| 27123  | 7590        | 04/21/2004           | EXAMINER            |                  |
| MORGAN & FINNEGAN, L.L.P.<br>345 PARK AVENUE<br>NEW YORK, NY 10154 |             |                      | LANDSMAN, ROBERT S  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1647                |                  |

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/787,334

Applicant(s)

CHEMTOB ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-5 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *1. Formal Matters*

- A. Amendment A, dated 1/29/04, has been entered into the record.
- B. Claims 1-5 and 10 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### *2. Claim Objections*

- A. The objection to claim 5 has been withdrawn since Applicants amended the claim to remove the term "mixture."

### *3. Claim Rejections - 35 USC § 112, first paragraph – new matter*

- A. Claims 1-5 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have amended claim 1 to recite the limitation "and provided that the antagonist is not native prostaglandin F2 receptor." However, there is no support for this limitation in the specification. **This is a new matter rejection.**
- B. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have amended claim 2 to recite "has about 88% homology." The Examiner apologizes for suggesting to Applicants to amend this claim to recite "88%" instead of "90%." The Examiner suggested this based on claim 1. However, the Examiner noticed that, unlike previously believed, claim 2 does not depend from claim 1, nor does claim 2 recite anything to the effect of "at least one substitution" to SEQ ID 1 or 4-11. Therefore, there is no support for "88%" in the specification. **This is a new matter rejection.** The Examiner apologizes for this suggestion.

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**4. Claim Rejections - 35 USC § 112, first paragraph - scope of enablement**

A. The rejection of claims 3, 4 and 10 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments that one of skill in the art would accept the in vitro data as being indicative of successful treatment in humans and that there is a strong correlation between uterine contractions and successful prevention of premature delivery of a fetus in vivo or prevention of dysmenorrhea.

**5. Claim Rejections - 35 USC § 102**

A. The rejection of claims 1 and 5 under 35 USC 102 as being anticipated by Abromovitz et al. has been withdrawn in view of Applicants' amendment to the claims to recite that the F2 receptor is not a native F2 receptor. However, this raises issues of new matter as seen above under 35 USC 112, first paragraph.

B. Claims 1 and 5 are rejected under 35 USC 102 as being anticipated by Rehwald et al. (FEBS Letters 443). The claims recite a prostaglandin F2 antagonist comprising SEQ ID NO:1 or 4-11 wherein the antagonist is not native F2 receptor. Rehwald teach a mutant rat F2 receptor. Rehwald is silent as to the sequence of the rat receptor. In absence of evidence to the contrary, this receptor comprises one of SEQ ID NO:1 or 4-11. This receptor still binds PGF2-alpha, demonstrating that it can be used as an antagonist. Since this receptor has been mutated, it is not native.

**6. Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lake et al. (FEBS 355) in view of Rehwald et al. (FEBS 443). The claims recite a prostaglandin F2 antagonist comprising SEQ ID NO:1 or 4-11 wherein the antagonist is not native F2 receptor. Lake teach the human and rat F2 receptors. However, Lake do not teach a non-native F2 receptor. However, Rehwald do teach a mutant rat F2 receptor. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the

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present invention to have produced a mutant human (or rat) receptor by making at least a single amino acid change to the native human or rat F2 receptor. These mutant receptors of Rehwald are antagonists since they bind PGF2-alpha (Abstract). Since these receptors are mutants, they are not "native F2 receptors." It would be expected that single amino acid substitutions could still be made in the native human receptor wherein the receptor would still retain binding affinity.

### **7. Conclusion**

A. No claim is allowable.

### **8. Note**

A. Though the Examiner was only able to find the above references, it should be noted that any FP2 receptor with a point mutation, or a truncated or chimeric FP receptor would likely meet the limitation of claims and 5.

### **Advisory information**

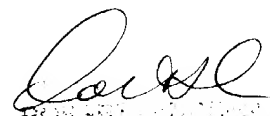
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
April 20, 2004

  
ROBERT LANDSMAN  
PATENT EXAMINER